

Docket No.: V9661.0072

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Cyrus R. Kumana et al.

Confirmation No.: 5138

Application No.: 10/669,869

Group Art Unit: 1616

Filed: September 23, 2003

Examiner: F.I. Choi

For:

FORMULATION OF ORAL

COMPOSITIONS COMPRISING

ARSENIC TRIOXIDE AND METHODS OF

USE THEREOF

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:

	This IDS is being filed before the First Office Action ¹ .
X	This IDS is being filed after the issuance of the First Office Action but before

DOCSNY-201623v01

¹ The IDS should, where possible, include a certification under 37 CFR § 1.97(e).

PTO/SB/17 (01-06)
Approved for use through 7/31/2006. OMB 0651-0032
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bees pursuant to the Consolida	Complete if Known Application Number 10/669,869-Conf. #5138						
FEE TRA	Application Nun		September 23, 2003				
	Filing Date						
For	First Named Inv		Cyrus R. Kumana F. I. Choi				
X Applicant claims sma	Il entity status.	See 37 CFR 1.27	Art Unit		316		
TOTAL AMOUNT OF PA	YMENT	(\$) 180.00	Attorney Docket	No. V	9661.0072		
METHOD OF PAYMEN	IT (check all t	nat apply)					
Check X Credit	Card N	Ioney Order No	one Other (please identif	y):		
Deposit Account Dep	osit Account Numb	er: 50-2215 Deposit A	count Name: D	ickstein Sha	apiro Morin &	Oshinsky	LLP
For the above-ider	tified deposit a	account, the Director	is hereby authorize	ed to: (check	all that apply)		
Charge fee(s) indicated bel	ow	Charg	e fee(s) indic	cated below, ex	cept for the	filing fee
Charge any a	additional fee(s) or underpayment o	f X Credit	any overpay	ments		
	37 CFR 1.16						
FEE CALCULATION (on filing or may	be subjec	t to a surcha	rge.)	
1. BASIC FILING, SEARC			ARCH FEES	EYAMINIA	ATION FEES		
		Small Entity	Small Entity	LAMINA	Small Entity		
Application Type	Fee (\$)	Fee (\$) Fee (Fee (\$)	Fee (\$)	Fees Pa	id (\$)
Utility	300	150 500		200	100		
Design	200	100 100		130	65		
Plant	200	100 300		160	80		
Reissue	300	150 500		600	300		
Provisional	200	100	0	0	0		
2. EXCESS CLAIM FEES							mall Entity Fee (\$)
Fee Description	din - Daismas					Fee (\$) 50	25
Each claim over 20 (include Each independent claim or						200	100
Multiple dependent claims		g Keissues)				360	180
		ee (\$) Fee	Paid (\$)	Mud	tiple Depende		100
42 - 20 =	0 x	0 =	0	<u>Fee</u>		ee Paid (\$)	
HP = highest numer of total cla					77		
Indep. Claims Extra	Claims F	ee (\$) Fee	Paid (\$)	VIII.			-
4	0 ×	0 =	0				
HP = highest numer of indepen	dent claims paid f	or, if greater than 3.					_
3. APPLICATION SIZE FEE							
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50							
sheets or fraction ther	eof. See 35 U	.S.C. 41(a)(1)(G) and	1 37 CFR 1.16(s).	oi siliali cili	ity) for each ac	iditional 50	
	Extra Sheets		additional 50 or fra	tion thereof	Fee (\$)	Fee Pa	aid (\$)
- 100 = /50 (round up to a whole number) x =							
4. OTHER FEE(S)						Fees P	aid (\$)
Non-English Specification, \$130 fee (no small entity discount)							
Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00							
SUBMITTED BY							
Signature	RI)	Registration No. (Attorney/Agent)	55,749	Telephone	(212) 277-	-6500
Name (Print/Type) Cindy Y	ang				Date	June 20,	2006

I hereby certify that this correspondence is 262736904 U.S. in an envelope addressed to:	being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the
date shown below.	
Dated:	Signature: Cindy Yang

	al No.: 10/669,869 Docket No.: V9661.0072 ion Disclosure Statement (6/20/06)
	issuance of a Final Office Action ² .
	This IDS is being filed after the issuance of a Final Office Action but before payment of the Final Fee ³ .
Certifica	tions:
	If checked, the undersigned makes the following statement(s):
	Statement under 37 CFR 1.97(e):
	Each item of information contained in this information disclosure statement
	was first cited in any communication from a foreign patent office in a
	counterpart foreign application not more than three months prior to the filing
	of this information disclosure statement; and/or
	No item of information contained in this information disclosure statement
	was cited in a communication from a foreign patent office in a counterpart
	foreign application, and, to the knowledge of the undersigned after making
	reasonable inquiry, no item of information contained in this information
	disclosure statement was known to any individual designated in §1.56(c)
	more than three months prior to the filing of the information disclosure
	statement.
	Statement under 37 CFR 1.704(d):
	Each item of information contained in this information disclosure statement
	was cited in a communication from a foreign patent office in a counterpart

application and this communication was not received by any individual

 $^{^2}$ The IDS must include either a certification under 37 CFR \S 1. 97(e) or the fee set forth in 37 CFR \S 1.17(p).

³ The IDS must include both a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

U.S. Serial No.: 10/669,869 Docket No.: V9661.0072

Information Disclosure Statement (6/20/06)

designated in 1.56(c) more than thirty days prior to the filing of this information disclosure statement.

Fee Required by 37 CFR 1.97(c)(2) or 1.97(d)(2):

X If checked, the fee of \$180.00 set forth in 37 CFR 1.17(p) is attached.

Materiality:

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

U.S. Serial No.: 10/669,869 Docket No.: V9661.0072

Information Disclosure Statement (6/20/06)

Please charge our Credit Card in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). Credit Card Payment Form SB-2038, with a signature from an authorized cardholder, is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2215, under Order No. V9661.0072.

Dated: June 20, 2006

Respectfully submitted

Charles E. Miller

Registration No. 24,576

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OSHINSKY LLP

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Attorneys for Applicants

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 262736904 US, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.
Dated: Signature: Cindy Yang

PTO/SB/08a/b (07-05)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

1 1 of Sheet

to respond to a collection of information unless it contains a valid OMB control number.				
Complete if Known				
Application Number 10/669,869-Conf. #5138				
Filing Date	September 23, 2003			
First Named Inventor	Cyrus R. Kumana			
Art Unit	1616			
Examiner Name	F.I. Choi			
Attorney Docket Number	V9661.0072			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		AU, WING-YAN et al., "Oral arsenic trioxide in the treatment of relapsed acute promyelocytic leukemia", <i>Blood</i> 102(1):407-408 (July 1, 2003)	
,	_	AU, WING Y. et al., "Treatment of Relapsed Acute Promyelocytic Leukemia by Arsenic-Based Strategies without Hematopoietic Stem Cell Transplantation in Hong Kong: A Seven-Year Experience", Blood (ASH Annual Meeting Abstracts), 104:Abstract 395 (2004)	
		AU, WING-YAN et al., "Successful Treatment of Relapsed Acute Promyelocytic Leukemia in a Patient Receiving Continuous Ambulatory Peritoneal Dialysis With Oral Arsenic Trioxide", Arch Intern Med., 165:1067-1068 (2005)	
		AU, WING-YAN et al., "Elemental arsenic entered the cerebrospinal fluid during oral arsenic trioxide treatment of meningeal relapse of acute promyelocytic leukemia", <i>Blood</i> , 107(7):3012-3013 (2006)	
		KUMANA, C.R. et al., "Systemic availability of arsenic from oral arsenic-trioxide used to treat patients with hematological malignancies", <i>Eur J Clin Pharmacol</i> , 58:521-526 (2002)	
		SIU, CHUNG-WAH et al., "Effects of oral arsenic trioxide therapy on QT intervals in patients with acute promyelocytic leukemia: implications on long-term cardiac safety", <i>Blood</i> , 0:2006-01-0054 (2006)	
			L

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Signature Considered	Examiner	Date	
	Signature	Considered	

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.